**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 4/20/2026-4/29/2026*<br>FEI NUMBER<br>3020705743 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dan R. Faga, CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| AnaptysBio | 10770 Wateridge Cir Ste 210 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| San Diego, CA 92121-5801 | Sponsor |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

Failure to provide investigators with the information needed to conduct the study properly and ensure proper monitoring of the study.

The inspection of clinical studies (b) (4) and (b) (4) revealed that the Sponsor failed to adequately oversee and monitor (b) (4), the CROs responsible for monitoring.

Specifically,

1. There was an absence of a study-specific monitoring plan between April 2022 and October 2022. In April of 2022, monitoring responsibilities were transferred from (b) (4) to individual monitoring CROs based on region – (b) (4) These CROs followed the *AnaptysBio Monitoring Plan* which was developed in October 2022, resulting in an approximate 6 month gap in monitoring plans.
2. Data queries within the Medidata RAVE EDC were not resolved for a period of 9-13 months. Per the *AnaptysBio Monitoring Plan (03Oct2022)* the timeline for query resolution is approximately 3 business days from date of query issued.
    - For subjects (b) (6) and (b) (6), queries flagging anomalous FSH data entries were first opened in June 2022 and September 2022, respectively. Formal DM queries confirming that the FSH was not collected per protocol – an acknowledged protocol deviation – were not resolved until July 2023, representing resolution timelines of approximately 10-13 months.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Farwa Z Razvi, Investigator<br>X Farwa Z Razvi Investigator Signed By: 2004050414 Date Signed: 04-29-2026 11:35:32 | 4/29/2026 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 4/20/2026-4/29/2026* |
| | FEI NUMBER<br>3020705743 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dan R. Faga, CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| AnaptysBio | 10770 Wateridge Cir Ste 210 |
| CITY, STATE, ZIP CODE, COUNTRY<br>San Diego, CA 92121-5801 | TYPE ESTABLISHMENT INSPECTED<br>Sponsor |

- For subject (b) (6) a query regarding incorrect childbearing potential classification – a data point directly relevant to subject eligibility and required protocol assessments – was opened in December 2022 and was not resolved until September 2023, a period of approximately 9 months.

3. Monitoring reports were not signed for various unblinded interim monitoring visits (IMVs). Per the *AnaptysBio Monitoring Plan*, the site visit report must be approved by the Report Reviewer and signed off by the CRA no later than 15 weekdays from the visit.
   - For site 10-101, six IMV reports were not signed by the CRA and/or a secondary reviewer.
   - For site 10-108, two IMV reports were not signed by the CRA and/or a secondary reviewer.
4. There was no site qualification documentation for site 42-107. Innovaderm was the CRO utilized for site selection prior to April 2022. Per the *Innovaderm Monitoring Plan* and *Site Identification, Feasibility, and Selection* SOP, each site must submit a Feasibility Questionnaire prior to the Site Qualification Visit (SQV), sponsor approval of the site must be obtained following the SQV, and sites must be provided with all essential documents prior to study initiation. These items could not be located in the TMF for site 42-107.

***DATES OF INSPECTION**
4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Farwa Z Razvi, Investigator<br>X Farwa Z Razvi Investigator Signed By: 2004050414 Date Signed: 04-29-2026 11:35:32 | 4/29/2026 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."